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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/717,641	11/21/2000	Lisa J. Gerrard	P0645P4D2C3	9837

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06/17/2003

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EXAMINER

LAMBERTSON, DAVID A

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 06/17/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/717,641

Applicant(s)

GERRARD ET AL.

Examiner

David A. Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 89 and 91-100 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Receipt is acknowledged of a reply, filed April 2, 2003 as Paper No. 12, to the previous Office Action. Amendments were made to the claims. Specifically, claim 90 was cancelled.

Claims 89 and 91-100 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, Paper No. 10, mailed October 2, 2002, that is not addressed in this action has been withdrawn.

All rejections of record in the previous Office Action are withdrawn. In view of the new grounds of rejection, applicant's arguments directed to the now withdrawn rejections are moot.

Priority

Applicant's claim for domestic priority to US applications 07/621,667, 07/683,400, 07/715,300 and 07/743,614 under 35 U.S.C. 120 is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 89 and 91-100 of this application. Specifically, there is no literal support in the applications wherein a suppressible termination codon is between or adjacent to the first and second genes. As such, priority is only granted to the filing date of PCT/US91/09133, December 3, 2003.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

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international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 89, 91, 93 and 94 are rejected under 35 U.S.C. 102(e) as being anticipated by Huse (US Patent No. 5,770,434, priority date of September 28, 1990; see entire document). **This is a new rejection that is not necessitated by amendment.**

Huse teaches the expression of random peptides on the surface of M13 filamentous bacteriophage by combining random oligonucleotides functionally linked both to gVIII coat protein and to expression elements in the form of a single vector (see for example column 10, lines 37-65). The purpose of the gVIII coat protein is to target the random peptide to the outer surface of the phage. The vector contains stop codons downstream of the random peptide, between the random peptide and the phage coat protein, and the stop codon can either be an amber, ochre or opal suppressible stop codon (see for example column 11, line 49 to column 12, line 16). This results in the expression of a fusion protein between a first polypeptide and a second polypeptide, wherein the second polypeptide is at least a portion of a filamentous bacteriophage coat protein, wherein a suppressible stop codon is located between the two polypeptides (see for example column 4, lines 16-32). Huse also anticipates host cells comprising these vectors (see for example column 4, lines 31-32).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 92 and 95-100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huse as applied to claims 89, 91, 93 and 94 under 35 USC 102(e), in view of Ladner *et al.* (US 5,223,409, IDS reference #5, priority date of September 2, 1988; see entire document; henceforth Ladner). **This is a new rejection that is not necessitated by amendment.**

Huse teaches all of the elements set forth above under 35 USC 102(e), which are incorporated into the rejection under 35 USC 103(a).

Huse does not specifically teach the use of the gIII coat protein to target the random peptide to the surface of the phage particle.

Ladner teaches a method of phage display, and the resulting products therein, using a number of different phage coat proteins. This includes the filamentous phage M13 coat proteins encoded by gene III and gene VIII (see for example column 51, lines 46-68), wherein Ladner teaches that either gIII or gVIII represents a highly preferred coat protein for the display of random peptides on the surface of the phage particle (see for example column 56, lines 63-66). The use of these coat proteins is attractive because the processing of the coat protein is well understood (see for example column 55, lines 37-53). Finally, Ladner points to teachings where an antibody fragment was fused to coat protein III of a bacteriophage.

It would have been obvious to combine the teachings of Huse and Ladner because both teachings regard the display of random peptides of the surface of a phage particle, using the coat proteins of the m13 filamentous bacteriophage. The ordinary skilled artisan would have been motivated to combine the teachings of Huse and Ladner in order to use coat proteins that were well understood in terms of their processing (as taught by Ladner), and could therefore be readily

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manipulated for the purpose of displaying random peptides on the surface of a phage particle.

Absent evidence to the contrary, and given the teachings in the prior art at the time of the invention, the ordinary skilled artisan would have had a reasonable expectation of success when practicing the invention as taught by Huse and Ladner.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 89 and 91-100 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6, 7 and 14 of U.S. Patent No. 6,040,136 (henceforth the '136 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are obvious in view of claims 12 and 14 of the '136 patent. **This is a new rejection that is not necessitated by amendment.**

Claim 12 (incorporating claims 1,6 and 7 by dependency) of the '136 patent reads on a phagemid expression vector expressing a fusion gene comprising a first gene encoding a first polypeptide and second gene encoding at least a portion of a phage coat protein, wherein the coat

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protein is from gene III, and wherein a suppressible stop codon is located between the first and second genes of the fusion. Claim 14 of the '136 patent reads on a phagemid expression vector expressing a fusion gene comprising a first gene encoding a first polypeptide and second gene encoding at least a portion of a phage coat protein, wherein the first gene can encode an immunoglobulin (i.e., an antibody).

Claim 12 is a species claim that anticipates the genus claims 89 and 91-97 of the instant application. Claim 12 recites all of the limitations of the instant claims, additionally reciting the limitation wherein the vector does not contain a further gene encoding a mature phage coat protein. Because this claim falls within the broad genus of claims 89, 91-97, this claim necessarily anticipates the instant claims, therefore the instant claims are made obvious by claim 12. It is noted that the vector must be maintained in a host cell, therefore the host cells are obvious in view of the vector. Furthermore, the gene fusion is contained within the vector, therefore the gene fusion is also obvious in view of the vector.

Claims 98-100 are obvious in view of claims 12 and 14 of the '136 patent. The limitation of claim 14 recites a Markush group of peptides that can comprise the first gene of the fusion polypeptide. It would have been obvious to the ordinary skilled to combine the limitations of claim 14 with those of claim 12 because the limitations of claim 12 indicate that a first gene must be chosen, and claim 14 exemplifies genes that can be selected. The ordinary skilled artisan would have been motivated to combine the limitations of claims 12 and 14 because the first genes exemplified in claim 14 were preferred first gene of the vector claimed in claim 1, from which claim 12 depends. Absent evidence to the contrary, there would be a reasonable

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expectation of success when combining the limitations of claims 12 and 14 to arrive at the instant claims 98-100.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the co-pending application. Also, if both patents are issued and the patent resulting from the instant claims was issued and transferred to an assignee different from the assignee holding the '136 patent, then two different assignees would hold a patent to the same claimed invention and thus improperly there would be possible harassment by multiple assignees.

Claims 89 and 91-100 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 32-34 of U.S. Patent No. 5,750,373 (henceforth the '373 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are genus claims that are anticipated by the specific claims of the '373 patent. **This is a new rejection that is not necessitated by amendment.**

Claim 34 of the '373 patent reads on an M13 phagemid comprising a fusion polypeptide comprising a first gene (which can be an antibody) fused to the M13 gene III coat protein, wherein a stop codon is placed between the two genes. This claim is a specific embodiment of the generic claims 89 and 91-100 of the instant application. It is noted that the phagemid must replicate in a host cell, therefore the vector anticipates the host cells containing the phagemid. Furthermore, in order to be in possession of the phagemid comprising the gene fusion, one must be in possession of the gene fusion, therefore the gene fusion is anticipated by the phagemid.

Allowable Subject Matter

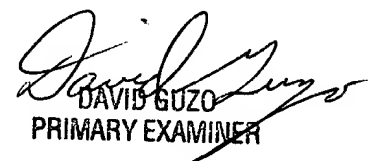
No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson
June 12, 2003


DAVID GUZO
PRIMARY EXAMINER